

Application No.: 10/822,200  
Amendment and Response filed on April 26, 2005  
Reply to Office Action of January 26, 2005  
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### **REMARKS**

Reconsideration of the application as amended is respectfully requested.

#### **Status of the Claims**

Claims 29-44 are presently pending. Claims 1-28 have been previously cancelled.

#### **Discussion of the Amendments to the Specification**

The specification has been amended to correct obvious typographical errors. In particular, in the section entitled "Cross-Reference to Related Applications," the specification has been amended to change "Serial No. 09/008/265" to "Serial No. 09/008,265" and to change "reference" to "reference." Moreover, that section also has been amended to indicate that U.S. Application No. 09/525,710 has issued as U.S. Patent No. 6,428,571. No new matter has been added by way of these amendments.

#### **Discussion of the Rejection Under 35 U.S.C. § 103(a)**

Claims 29-44 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,619,641 to Schanzer (hereinafter "Schanzer") in view of U.S. Patent No. 6,521,284 to Parsons et al. (hereinafter "Parsons"). In particular, the Examiner alleges that Schanzer discloses a first tubular structure having a first "thickness/porosity" and a second tubular structure having a second "thickness/porosity" wherein a resealable layer made of silicone is interposed between the tubular structures. The Examiner takes the position that Schanzer "does not disclose the use of *ePTFE* or adherence [sic] or a flowable material." (Office Action, page 3). The Examiner then concludes that it would have been obvious to substitute the ePTFE of Parsons for the PTFE material of Schanzer. The rejection under 35 U.S.C. § 103(a) is respectfully traversed for the reasons set forth below.

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To clarify remarks of record made in connection with parent U.S. Application No. 09/525,710 (which is now U.S. Patent No. 6,428,571), Applicants note that Schanzer at col. 2, lines 52-56, discloses a tube "made entirely from GORE-TEX reinforced PTFE tubing developed by W.F. Gore & Associates, Inc. by rapidly stretching highly crystalline unsintered polytetrafluoroethylene." One of ordinary skill in the art would appreciate that PTFE stretched in such a manner is ePTFE. However, notwithstanding this disclosure, the combination of Schanzer and Parsons still does not render claims 29-44 obvious for the reasons set forth below.

To establish a *prima facie* case of obviousness, the Examiner must establish that the cited combination of references teach or suggest every limitation of the claimed invention. Moreover, the Examiner must establish not only that there is some motivation to combine the teachings of the cited references, but also that there is a reasonable expectation of achieving the claimed invention upon doing so. *See* M.P.E.P. § 2142. The Examiner has failed to make these requisite showings.

Claims 29-44 are all directed to a multi-layered ePTFE graft having a first ePTFE tubular structure, a second ePTFE tubular structure, and a self-sealing material interposed in between, wherein the porosity of each of the tubular structures is different. Schanzer, however, fails to disclose, teach or suggest such a graft.

Schanzer is directed to a double lumen tube for use as a graft in hemoaccess (see col. 1, line 63). The double lumen tube has an inner tube, an outer tube, and a space in between the inner and outer tubes (see col. 2, lines 16-19). According to Schanzer, the space is filled with a self-sealing polymer such as a silicone rubber sealant (see col. 2, lines 22-25). Although Schanzer discloses the wall thickness of each of the tubes, there is no disclosure, teaching or

suggestion with regard to porosity. Indeed, one of ordinary skill in the art would appreciate that wall thickness and porosity are distinct properties and that one is not indicative of the other.

Moreover, Schanzer provides no motivation to provide a porosity differential between the inner and outer layers of the double lumen tube disclosed therein. In contradistinction to the grafts of the present application which have layers of different porosities to simultaneously facilitate tissue ingrowth and promote radial tensile strength (see, for example, page 5, lines 1-5, and page 7, lines 16-19, of the instant specification), there is no appreciation in Schanzer of utilizing tubular layers of different porosities to achieve such objectives. In fact, the double lumen tube of Schanzer was specifically designed to overcome the need for immediate tissue ingrowth so that it could be used for hemoaccess immediately upon implantation (see col. 1, lines 19-22, and 52-53). Thus, the primary reference upon which the Examiner relies, at best, teaches away from the present invention.

The disclosure of Parsons does not remedy the basic deficiencies of Schanzer. Indeed, viewing Parsons for what it teaches as a whole, that reference cannot be considered suggestive of, or providing motivation towards, the present invention as defined by the pending claims. Moreover, given the disparate teachings of Schanzer and Parsons, one of ordinary skill in the art would not even be motivated to combine their teachings.

Parsons is directed to impregnating the pores of a porous material such as ePTFE with a cross-linkable composition that may form a hydrogel (see col. 2, lines 28-31 and 38-41). Although Parsons discloses grafts with "self-sealing characteristics" that may be made by impregnating a porous substrate with a cross-linkable composition (see col. 10, line 64-col. 11, line 1), there is no disclosure, teaching or suggestion of a graft having a first tubular structure, a second tubular structure, and a self-sealing material interposed in between, let alone a disclosure,

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teaching or suggestion of such a graft where the porosity of each of the tubular structures is different. Indeed, Parsons was cited only for its disclosure with regard to ePTFE.

In view of the foregoing, claims 29-44 are not obvious in view of Schanzer in combination with Parsons. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a) with regard to claims 29-44.

**Discussion of the Obviousness-Type Double Patenting Rejections**

Claims 29, 32, 34-35, 37, 40-41, and 43-44 stand rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-15 of U.S. Patent No. 6,428,571. Moreover, claims 29-44 stand rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-25 of U.S. Patent No. 6,719,783. Enclosed is a terminal disclaimer pursuant to 37 C.F.R. § 1.321(c) disclaiming the terminal portion of any patent issuing on the present application which would extend beyond the expiration date of U.S. Patent No. 6,428,571 and the expiration date of U.S. Patent No. 6,719,783. Entry of the terminal disclaimer is respectfully requested. The terminal disclaimer is believed to obviate the obviousness-type double-patenting rejections.

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**Other Remarks**

The Examiner has indicated that U.S. Patent No. 6,319,279 (to Shannon et al.), U.S. Patent No. 5,466,509 (to Kowligi et al.), and U.S. Patent No. 5,246,452 (to Sinnott) are considered pertinent to Applicants' disclosure. None of these references, however, disclose, teach or suggest the current invention as defined by the pending claims.

**Concluding Remarks**

The claims are believed to be allowable over the art and the application in good and proper form for allowance. The Examiner is invited to contact the undersigned if he has any questions regarding this submission or, if in his opinion, a teleconference call would expedite prosecution of the subject application.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



Christina L. Warrick  
Registration No.: 45,690  
Attorney for Applicants

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(973) 331-1700